VIRGINIA:

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
DANVILLE DIVISION

LOIS LORRAINE ADKINS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No.: 4:07-cv-53
	)	
CYTYC CORPORATION, ET AL.,	)	
	)	
Defendants.	)	

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION
TO DEFENDANTS' MOTION TO DISMISS

Plaintiff, Lois L. Adkins, by counsel, files this Memorandum of Law in Opposition to Defendants' Motion to Dismiss stating as follows:

I. Question Presented:

Defendants' Motion to Dismiss raises several issues regarding preemption of common-law actions by federal law, but, given the Supreme Court's recent holding in Riegel v. Medtronic, Inc., 552 U.S. ___, 128 S.Ct. 999, No. 06-179 (Feb. 20, 2008), only the following questions are of import:

1) Are Adkins' claims that Defendants' corporate representative was negligent expressly preempted by the Medical Device Amendments (MDA) despite the fact that her claims are not related to the safety and effectiveness of the NovaSure device;

And,

2) Are those claims impliedly preempted in the absence of any indication from Congress that it intends the MDA to preempt those types of actions?

II. Statement of the Case:

On November 14, 2007, Adkins filed her Complaint alleging that she was injured by Defendants' NovaSure endometrial ablation device and by the negligent actions of Defendants' corporate representative. The Complaint specifically alleged four causes of action. First, Adkins alleged that Defendants breached the implied warranty of merchantability by selling a product that was unreasonably dangerous for its intended purposes. See Compl. ¶¶ 20-23. Second, Adkins alleged that Defendants breached an express warranty by selling a product that was unsafe for its intended uses. See Compl. ¶¶ 24-27. Third, Adkins alleged that Defendants were negligent by improperly designing and manufacturing aspects of the Novasure device, and by failing to provide adequate warnings. See Compl. ¶¶ 28-29. Finally, Adkins, under an agency theory, alleged that Defendants were negligent when their corporate representative, who was present throughout the ablation procedure and advised and directed Adkins' doctor on how to use the NovaSure device, breached his duties to ensure that the device was operating correctly and that Adkins' doctor used the device properly. See Compl. ¶¶15-18, 30-32.

On April 3, 2008, Defendants filed their Motion to Dismiss Plaintiff's Complaint arguing that each of her claims is preempted by the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act (MDA), 21 U.S.C. § 360c et seq. Defendants incorrectly interpret Adkins' Complaint as alleging three causes of action solely related to the design, manufacture and labeling of the Novasure device: 1) breach of implied warranty, 2) breach of express warranty, and 3) negligence. See Memorandum of Law in Support of Defendants' Motion to Dismiss, p. 1, ¶1. For example, Defendants believe that Adkins only claims that they "negligently designed and manufactured the medical device and failed to provide adequate warning either through its labeling or its corporate representative." Id., see also Id., p. 10, ¶1 (stating, "each of the Adkins'

claims seeks to hold Cytyc liable on the ground that Cytyc should have been [sic] designed, manufactured, or labeled NovaSure pursuant to different or additional requirements imposed under state law…").

At no point have Defendants addressed Adkins' claims that their corporate representative breached his duties to ensure the device was operating and being operated properly. More specifically, Defendants have neither disputed that their corporate representative owed a duty to Adkins, nor that, by his action or inaction, he breached that duty.

III. Arguments and Authorities:

A. Standard of Review:

The limited function of the Rule 12(b)(6) motion to dismiss, like the demurrer in Virginia state court practice, is to test "the sufficiency of the complaint." Gasner v. Town of Dinwiddie, 162 F.R.D. 280, 281 (E.D. Va. 1995), aff'd 103 F.3d 351 (4th Cir. 1996). Most importantly, the Rule 12(b)(6) motion "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." Id. Therefore, when approaching a 12(b)(6) motion to dismiss, the Court must presume that all facts alleged in Plaintiff's Complaint are true, make all reasonable inferences in favor of Plaintiff, and not dismiss any count of the Complaint unless it appears, beyond doubt, that recovery would be impossible under any set of facts that could be proven. See Samuel v. Rose's Stores, Inc., 907 F.Supp. 159, 162 (E.D. Va. 1995). In fact, the Court should "accept all well-pleaded allegations in Plaintiff's complaint as true and draw all reasonable factual inferences from those facts in Plaintiff's favor." Briggs v. Waters, 455 F.Supp.2d 508, 512 (E.D.Va. 2006)(citing Chao v. Rivendell Woods, Inc., 415 F.3d 342, 346 (4th Cir. 2005)).

As a result, "[a] Rule 12(b)(6) motion should only be granted if, after accepting all well-pleaded allegations in Plaintiff's complaint as true and drawing all reasonable inferences from those facts in Plaintiff's favor, it appears certain that Plaintiff cannot prove any set of facts in support of [her] claim entitling [her] to relief." Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999).

Construing the facts as alleged in her Complaint as true, Adkins has set out a claim upon which relief can be granted. Namely, she has alleged that Defendants, through their corporate representative, had several duties, that they breached those duties, and that the breach was a cause of her injuries. She therefore asks the Court to overrule Defendants' Motion to Dismiss.

B. Preemption Doctrine:

The doctrine of preemption is rooted in the Supremacy Clause of the United States Constitution, and "state laws that 'interfere with, or are contrary to the laws of Congress, made in pursuance of the Constitution' are invalid." Wisconsin Public Intervenor v. Mortimer, 501 U.S. 597, 604 (1991), quoting Gibbons v. Ogden, 22 U.S. 1 (1824). Of course, "when Congress does exercise its paramount authority, [it] may determine how far its regulation shall go....Congress may circumscribe its regulation and occupy only a limited field. When it does so, state regulation outside that limited field and otherwise admissible is not prohibited." Kelly v. State of Washington ex rel. Foss Co., 302 U.S. 1, 10 (1937). Therefore, it is "the purpose of Congress [that] is the ultimate touchstone of pre-emption analysis." Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (citation omitted).

Congress may make its purpose explicit by the terms of its Act, or Congress may embed its purpose in the scope, reach or goal of the Act. Congress's implied purpose may be determined from the following situations: if the "scheme of federal regulation is so pervasive"

that a court can infer that Congress left no room for State action; if the subject matter of the federal regulation touches a subject in which the federal interest is so dominant that state laws on the same subject cannot be enforced; or if Congress's goals display a clear "purpose to preclude state authority." Wisconsin Public Intervenor, 501 U.S. at 605 (citations omitted).

In any event, "the intent to supersede...is not to be inferred from the mere fact that Congress has seen fit to circumscribe its regulation and to occupy a limited field. In other words, such intent is not to be implied unless the Act of Congress, fairly interpreted, is in actual conflict with the law of the State." Kelly, 302 U.S. at 12, quoting, Savage v. Jones, 225 U.S. 501, 533 (1912); see also Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (stating "the historic police powers of the States are not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress.").

C. Express Preemption by the MDA.

On February 20, 2008, the United States Supreme Court decided Riegel, and addressed under what circumstances the MDA expressly preempts "common-law claims challenging the safety and effectiveness of a medical device given pre-market approval by the Food and Drug Administration (FDA)". 128 S.Ct. 1002. The Court held that the MDA superseded a plaintiff's lawsuit to the extent it challenged the safety and effectiveness of a Class III medical device given pre-market approval by the FDA.

The MDA provides the statutory framework for federal regulation of medical devices. It was enacted in 1976 following the Dalkon Shield cases when States began creating their own regulatory scheme for medical devices. See Riegel, 128 S.Ct. at 1013 (dissent of Ginsberg discussing statutory history of MDA). By its explicit terms, it only applies to medical devices. As the Riegel majority noted, "The...[MDA] established various levels of oversight for *medical*

devices, depending on the risks they present." Id. at 1003 (emphasis added). And in her dissent to the Riegel opinion, Justice Ginsberg noted that "Congress enacted the MDA 'to provide for the safety and effectiveness of *medical devices* intended for human use.'" Riegel at 1014, quoting 90 Stat. 539 (preamble) (emphasis added).

The MDA's preemption clause provides,

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect *with respect to a device* intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) *which relates to the safety or effectiveness of the device* or to any other matter included in a requirement applicable to the device under this chapter.

See Riegel at 1003, quoting 21 U.S.C. § 360k(a) (emphasis added). Basically this means that, without exception, the MDA preempts any state requirement regarding the safety and effectiveness of medical devices to the extent they are in conflict with one another.

To determine when this conflict exists, , the Riegel Court announced the following two-part analysis. First, a Court must consider whether the FDA has established requirements applicable to the device at issue. Id. at 1006. If so, the next question concerns whether the plaintiff's common-law claim is based upon requirements "'different from, or in addition to' the [FDA requirements], and [whether they] relate to safety and effectiveness." Id. quoting 21 U.S.C § 360k(a).

Although unstated by the Court, the threshold question before this two-part analysis can be reached is: does the plaintiff's claim challenge the safety and effectiveness of a device?

i. Status of Adkins' product liability claims after Riegel:

Under the MDA, Class III medical devices must undergo a "rigorous" premarket-approval process. See Riegel, 128 S.Ct. at 1003-1004 (describing the premarket approval process for Class III devices). Construing the FDA's premarket approval process as federal regulation of a medical device, the Court found it to be the key to its preemption analysis. See Id. at 1005, citing 21 U.S.C. § 360e(d)(6)(A)(i) (stating "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in the design specifications, manufacturing processes, labeling or any other attribute, that would affect safety and effectiveness."); and Id. at 1007 (stating "The FDA requires [the device] to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness."). Thus, under the two-part Riegel test, if the FDA has given pre-market approval to a Class III medical device, any common-law product liability claim directed to the safety and effectiveness of said device will be preempted by the FDA's regulation.

Adkins acknowledges that Defendants' NovaSure device is a Class III medical device that has received premarket approval, and must therefore be manufactured and labeled in strict accordance with FDA guidelines. Adkins concedes that her claims of breach of implied warranty, breach of express warranty and negligence, to the extent they fault the design, manufacture and labeling of the NovaSure device, are claims directed toward its safety and effectiveness. At their core, each of these claims alleges that Defendants produced a defective device, which was unsafe and ineffective for its use, and that this defect was a cause of Adkins' injuries. Following Riegel, these claims are likely preempted by the MDA.

Adkins maintains, however, that she has also stated claims of negligence against Defendants' corporate representative, that are not directed to the safety and effectiveness of the NovaSure device and that are not preempted by the MDA.

ii. Adkins' claims of Defendants' corporate representative's negligence are not expressly preempted by the MDA.

As discussed above, the MDA only operates to expressly preempt common-law actions when those actions 1) are directed toward a medical device, 2) the medical device has been regulated by the FDA, and 3) the common-law action is based on a state requirement "different from or in addition to" the FDA's regulations and those regulations are directed toward the device's safety and effectiveness. See Riegel, 128 S.Ct. at 1006. Adkins' allegations of Defendants' corporate representative's negligence are not expressly preempted by the MDA because her allegations neither fault, nor challenge the safety and effectiveness of, a medical device. For this reason, the two-part Riegel test is not applicable.

In this particular instance, Adkins has alleged that it was Defendants' corporate representative's negligence that caused her injuries. Thus, Adkins' claims are not related to the safety and effectiveness of the NovaSure device, rather, they are related to the safety and effectiveness of the corporate representative himself. Stated differently, Adkins' allegations do not implicate state requirements "different from or in addition to" the FDA's requirements because her allegations do not tread within the FDA's bailiwick, here, medical devices. Therefore, Adkins' allegations of negligence are directed only toward Defendants' corporate representative's actions and the express preemption provisions of the MDA do not apply.

iii. Adkins' claims of Defendants' corporate representative's negligence are not impliedly preempted by the MDA.

As discussed in Section III., B., supra, when determining whether a federal act will impliedly preempt a state or common-law action, Congress's intent "is the ultimate touchstone[.]" Cipollone, 505 U.S. at 516. Congress, through the MDA, provided the regulatory framework by which the FDA oversees the design, manufacturing and labeling of medical devices. See Riegel, 128 S.Ct. at 1002-1005. In that sense, its scheme of federal regulation is broad. But that scheme is not so pervasive as to indicate that Congress intended to preempt all common-law actions related to a medical device. If this were true, then a plaintiff would not be permitted to sue a medical professional who improperly used an FDA-regulated medical device and caused an injury.

In essence, Adkins has claimed that Defendants' corporate representative, or someone at his direction, used the NovaSure device and caused her injury. This type of claim is firmly rooted in matters of individual health and safety, "a field which the States have traditionally occupied." Medtronic v. Lohr, 518 U.S. 470, 485 (1996) (citations omitted). And without a clear manifestation of Congress's intent to supersede this claim, Adkins' claim cannot be impliedly preempted. Id.

Defendants suggest that Adkins merely seeks to enforce their compliance with FDA regulations. If this were true, then Defendants' position would be supported by Buckman v. Plaintiff's Legal Committee, 531 U.S. 341 (2000). There, the Court held that a "plaintiff's state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by federal law." Id. The Court based its decision in large part on its analysis that "policing fraud against federal agencies is hardly 'a field which the states have traditionally occupied....To the contrary,

the relationship between a federal agency and the entity it regulates is inherently federal in character[.]" Id. (citations omitted).

The plaintiff's claims in Buckman are clearly different than those asserted in the instant case. Here, Adkins does not raise a cause of action based on the relationship between Defendants and the FDA. Rather, she alleges a cause of action based on her relationship with Defendants' through their agent. There is and has been no federal regulation of that relationship, and Defendants have not provided any evidence suggesting otherwise. Defendants' interpretation of Plaintiff's claims is therefore incorrect, and Buckman lends no support to their argument.

IV. Conclusion:

WHEREFORE Adkins respectfully requests that the Court overrule Defendants' Motion to Dismiss with regard to Adkins' allegations of negligence against Defendants' corporate representative. These allegations are neither expressly preempted by the MDA because they are not directed toward the safety and effectiveness of a medical device, nor are they impliedly preempted by the MDA because Congress did not intend the MDA to supersede this type of common-law action.

Respectfully Submitted,

LOIS LORRAINE ADKINS

By: /s/ William Wirt Brock, IV
Of Counsel

S. D. Roberts Moore (VSB No. 3456)
William Wirt Brock, IV (VSB No. 67985)
GENTRY LOCKE RAKES & MOORE, LLP
800 SunTrust Plaza
P. O. Box 40013
Roanoke, VA 24022-0013
(540) 983-9300
Fax: (540) 983-9400

Frank N. Cowan, Esq.
CowanOwen PC
P.O. Box 35655
Richmond, VA 23235-0655
(800) 948-7160x319
Fax: (804) 330-3140

Counsel for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of April, 2008, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following:

David P. Callet, Esq. (calletd@gtlaw.com)
Geoffrey J. Greeves, Esq. (greevesg@gtlaw.com)
Robert P. Charrow, Esq. (charrwor@gtlaw.com)
Greenberg Trauring, LLP
2101 L Street, N.W., Suite 1000
Washington, DC 20037
Counsel for the defendants

/s/ William Wirt Brock, IV

Wm. Wirt Brock, IV (VSB No. 67985)
Attorney for Plaintiff
Gentry Locke Rakes & Moore, LLP
800 SunTrust Plaza
P.O. Box 40013
Roanoke, VA 24022-0013
540/983-9300
540/983-9400 facsimile
wirt_brock@gentrylocke.com